

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: William H. Fleming

Application No. 10/781,043

Filed: February 17, 2004

Confirmation No. 8393

For: ANAL HYGIENIC PAD AND METHOD
OF USE

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Examiner: Jacqueline F. Stephens

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PRE-APPEAL REQUEST FOR REVIEW

Applicant requests review of the final rejection in the referenced application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. Review is requested for the reasons stated below.

The Claimed Invention

The subject claims (which are provided as **Exhibit A**) are directed to a method for absorbing leakage from the anus of a subject by positioning a non-adhesive intergluteal absorbent pad external to the subject's anal orifice such that the pad is retained frictionally between the buttocks. The claimed method represents an important new approach to hygiene in which it has been discovered that anal leakage can be absorbed without applying an adhesive patch. The claimed method has gone against the explicit teaching of the primary reference of record (Cox) and determined that the buttocks surprisingly retain an intergluteal pad frictionally without the need for adhesive. The claimed method is neither disclosed nor suggested by the cited references, and the claims are therefore allowable.

35 U.S.C. 102(b) Rejection of Claims 1-43 and 49-52

Claims 1-43 and 49-52 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cox (U.S. Patent No. 5,695,484; **Exhibit B**).

Rejections under 35 U.S.C. § 102

As stated in the M.P.E.P § 2131 “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)” [emphasis added]. This section of the M.P.E.P. further states that “[t]he identical invention must be shown in as complete detail as is contained in the ... claim.’

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).” If a reference does not teach each and every element of the claims, an anticipation rejection over the reference is improper and must be withdrawn. Because Cox does not teach all of the elements of the independent claims, the pending rejection under 35 U.S.C. § 102(b) is improper and Applicant respectfully requests that the Office withdraw this rejection.

Claim 1 and all the independent claims recite the positive method step of positioning a non-adhesive intergluteal absorbent pad that is retained frictionally between the buttocks without an adhesive to attach the pad to the buttocks. Therefore, for a reference to anticipate this claim it must at least teach the elements of this method step. Cox does not teach positioning a non-adhesive pad and there is no anticipation. As was stated in the response filed September 12, 2007, the entire disclosure of Cox is only directed to adhesive pads and the use of those pads to occlude the anal opening. This is definitively stated in column 1, lines 31-32, which reads “[t]he present invention in its broadest terms, comprises a pad having a biocompatible adhesive on one side” [emphasis added]. Cox further teaches that these pads are positioned by adhering them to “the external tissue of the natal cleft.” Column 1, lines 57-58. Cox clarifies that the pad is adhered to the natal cleft by stating that “[b]ecause of the design of the pad, the direct pulling off of the patch would involve shearing the adhesive bond of the adhesive coating from the external skin of the natal cleft.” Column 2, lines 34-37. Cox also states that “the adhesive coating also maintains the anal pad in place.” Column 4, lines 21-24. Because Cox only teaches positioning non-adhesive pads by adhering them to the natal cleft (which is the cleft formed by the buttocks) with an adhesive this reference does not teach the claim element of frictionally retaining a non-adhesive pad between the buttocks without an adhesive to attach the pad to the buttocks. In fact, none of the embodiments of the pad disclosed in Cox are non-adhesive and the Office has

provided no evidence or pointed to any portion of Cox that teaches positioning a non-adhesive pad that is frictionally retained without the use of an adhesive. For at least the reasons above, Cox does not teach all of the elements of the pending claims and the rejection is improper.

The Office asserts that the adhesive free nipple portion of the device disclosed by Cox meets the limitation of being frictionally retained between the buttocks. Even if that is so, it does not cure the deficiencies of the rejection. Whether or not the nipple portion of the pad is frictionally engaged with the subject is of no consequence. In evaluating whether a claim is anticipated the entirety of the claim must be considered. In the current case, the claims all include the feature that the pad is frictionally retained between the buttocks external to the subject's anus without any adhesive to attach the pad to the buttocks. As discussed above, all of the devices disclosed by Cox, and methods of their use, rely on the presence of an adhesive to attach the Cox device to the buttocks of a subject. This adhesive is used to retain the Cox pad in position and to create a seal around the anus. Column 4, lines 21-24. Thus, contrary to the assertion of the Office, the pad disclosed by Cox does not have the feature of being frictionally retained between the buttocks external to the subject's anus without any adhesive to attach the pad to the buttocks. For this additional reason, Cox does not include all of the features present in the claims and the anticipation rejection is improper.

For at least the reasons presented above, Cox does not teach each and every limitation present in claims 1-43 and 49-52, and there is no anticipation.

Cox also does not render claims 1-43 and 49-52 obvious at least because a modification of Cox in which the pad is rendered non-adhesive (*i.e.* modified to be non-adherent) would frustrate or destroy the purpose and function of the Cox device, which is to provide an adhesive seal to prevent leakage from the anus and maintain the position of the pad by adhering it to the natal clef. Rendering the seal non-adhesive would interfere with its sealing function that is designed to prevent leakage around the adhesive pad. “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125.” M.P.E.P. 2143.01. Cox states that the required adhesive in the pad “not only

provides the seal preventing the leakage of discharges from the anal opening from beyond the anal patch, but the adhesive coating also maintains the anal patch in place during usage.” Column 4, lines 20-23. Cox also states that “[t]he adhesive coating must be relatively strong.” Column 4, lines 23-24. Therefore, it would not be obvious to eliminate the adhesive because that would disrupt the “seal preventing the leakage of discharges from the anal opening” and the pad would no longer function for its intended purpose. It would not be obvious to modify Cox to remove this adhesive coating because it would contravene the explicit teaching of Cox, which states that a strong adhesive *must be* present on the pad to adhere it to the user’s body for its intended purpose.

Rejections under 35 U.S.C. § 103(a)

Claims 44-48 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cox. As discussed previously, Cox does not teach the feature of positioning a non-adhesive pad that is frictionally retained between the buttocks without an adhesive to attach the pad to the buttocks. Cox teaches that the pad is positioned by adhering it to the natal cleft with an adhesive. Thus, any modification that renders the pad of Cox non-adhesive and therefore incapable of adhering to the natal cleft would be contrary to the teaching of Cox. For at least these reasons no *prima facie* case of obviousness has been established with respect to claims 44-48 and they are allowable. Applicant requests that the rejection be withdrawn.

Claims 16, 17, 29, and 30 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cox in view of Okuda (U.S. Patent No. 4,920,045; **Exhibit C**). The Office asserts that it would be obvious to modify the methods disclosed by Cox to perform a diagnostic test on fecal material as disclosed by Okuda. In determining obviousness “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” M.P.E.P. 2143.03. Claims 16, 17, 29, and 30 include the feature of positioning a non-adhesive pad that is retained frictionally between the buttocks without an adhesive to attach the pad to the buttocks. As discussed above, Cox does not teach this feature. This deficiency is not made up by Okuda because Okuda does not teach the positioning of any pad adhesive or otherwise. The asserted combination of Cox and Okuda does not teach or suggest each and every feature of claims 16, 17, 29, and 30 at least

because the references are devoid of any teaching of a pad that does not have an adhesive surface. For at least the above reasons, the Office has not presented a *prima facie* case of obviousness with respect to claims 16, 17, 29, and 30. Therefore, these claims are allowable, and Applicant requests that the rejection be withdrawn.

Concluding Statement

Applicant submits that the primary reference (Cox) does not teach or suggest a method for absorbing leakage from the anus of a subject by positioning a non-adhesive intergluteal absorbent pad. A *prima facie* case of obviousness has not been established by the Office action because the claimed subject matter is not disclosed or suggested by Cox or Okuda either alone or in combination. In addition, any modification of the cited references to produce the invention as claimed would be opposed to the teaching of the primary reference (Cox), which only teaches an adhesive pad. The cited references therefore fail to teach each and every element of claims 1-52 and do not provide any expectation that the claimed method will be successful. There is no motivation to produce the claimed methods, and consequently, claims 1-52 are allowable in view of the cited references. Applicant respectfully requests that all pending rejections be withdrawn.

Respectfully submitted,

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